IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA HUNTINGTON DIVISION

CHRISTOPHER FAIN and SHAUNTAE ANDERSON; individually and on behalf of all others similarly situated,

Plaintiffs,

CIVIL ACTION NO. 3:20-cv-00740 HON. ROBERT C. CHAMBERS

v.

WILLIAM CROUCH, et al.,

Defendants.

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY OF STEPHEN B. LEVINE, M.D.

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I. INTRODUCTION

The issue in this case is whether Defendants' policy of not providing insurance coverage for gender-confirming surgical care (the "Exclusion")¹ violates the Equal Protection Clause, Section 1557 ("Section 1557") of the Patient Protection and Affordable Care Act ("ACA" or "Affordable Care Act"), and the Medicaid Act's Comparability and Availability Requirements. Yet, Defendants have put forward an expert, Dr. Stephen Levine, whose opinions other federal courts have resoundingly dismissed. Moreover, Dr. Levine has not and cannot opine on the actual issue in this case. His opinions are (1) irrelevant because they are largely aligned with the relief Plaintiffs seek; (2) fail to create any material disputes of fact because the relevance of his opinions are outside the scope of the issue in this case and, regardless, cover topics the Fourth Circuit has already addressed; and (3) are unreliable, not based on scientific methodology, and devoid of probative value, thus risking unfair prejudice, confusion, undue delay and needless presentation of cumulative evidence. The Court should exclude Dr. Levine's opinions.²

II. LEGAL STANDARD

Federal Rule of Evidence 702 places "a special gatekeeping obligation" on a trial court to ensure that an expert's testimony is "relevant to the task at hand" and "rests on a reliable foundation." *Daubert v. Merrell Dow Pharm., Inc.,* 509 U.S. 579, 597 (1993); *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281 (4th Cir. 2021). The party offering the expert carries the burden of establishing admissibility by a preponderance of the evidence. *Cooper v. Smith & Nephew, Inc.*,

¹ To the extent Defendants omit coverage for other gender-confirming care, that is also part of the Exclusion. For example, as to puberty-delaying treatment, while Defendants have denied this care at least once, BMS's Medical Director agrees that it is "standard of care" for gender dysphoria, and Defendants have previously covered it. See Pls.' SJ Mem. at Pt. II(C), n.38.

² Expert Disclosure of Stephen B. Levine, M.D., signed February 18, 2022, is attached as Exhibit A to the concurrently filed Declaration of Carl S. Charles ("Charles Decl.").

259 F.3d 194, 199 (4th Cir. 2001). But "[t]he district court is the gatekeeper. It is an important role: 'Expert witnesses have the potential to be both powerful and quite misleading [;]" the court must "ensure that any and all scientific testimony ... is not only relevant, but reliable." *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 516 (S.D.W. Va. 2014), *as amended* (Oct. 29, 2014) citing *Cooper*, 259 F.3d at 199.

In determining whether the proposed expert is qualified, a trial court considers their "full range of experience and training." *Belk, Inc. v. Meyer Corp., U.S.,* 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (cleaned up). If the purported expert lacks the knowledge, skill, experience, training or education on the issue for which the opinion is proffered, the trial court must exclude the expert. *See, e.g., Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989); *Mod. Auto. Network, LLC v. E. All. Ins. Co.*, 416 F. Supp. 3d 529, 537 (M.D.N.C. 2019) (Biggs, J.), *aff'd*, 842 F. App'x 847 (4th Cir. 2021); *Tyree*, 54 F. Supp. 3d at 561. Even if the expert is deemed qualified, the trial court must consider the relevancy of the expert's testimony as "a precondition to admissibility." *Sardis*, 10 F.4th at 282 (cleaned up). Simply put, "if an opinion is not relevant to a fact at issue, Daubert requires that it be excluded." *Id.* at 281.

If deemed relevant, the trial court will inquire if the opinion is reliable, which focuses on "the principles and methodology" employed by the expert to assess whether it is "based on scientific, technical, or other specialized *knowledge* and not on belief or speculation." *Id.* at 281, 290 (cleaned up). When evaluating reliability, a court considers, among other things:

(1) whether the expert's theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error of the particular scientific technique; and (4) whether the technique is generally accepted in the scientific community.

Id.; see also Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 149-150 (1999); Daubert, 509 U.S. at 593-94. While trial courts have "broad latitude" to determine reliability, they must engage

in the gatekeeping process and not simply "delegate the issue to the jury." *Sardis*, 10 F.4th at 281. Even when an expert relies upon their experience and training in forming opinions, "[p]roposed testimony must be supported by appropriate validation—i.e., 'good grounds' based on what is known." *Tyree*, 54 F. Supp. 3d at 526 (citing *Daubert* 509 U.S. at 590). An expert cannot purport to have "considered the scientific literature" in forming their opinions but be unable to provide scientific support for some opinions. *Id*. Even though an expert "has experience, he must still base his opinions on a reliable, scientific method." *Id*. ("[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method.").

Finally, because "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it...[T]he judge in weighing possible prejudice against probative force under Rule 403...exercises *more* control over experts than over lay witnesses." *Daubert*, 509 U.S. at 595 (cleaned up) (emphasis added). As such, "the importance of [the] gatekeeping function cannot be overstated." *Sardis*, 10 F.4th at 283 (cleaned up).

III. ARGUMENT

As a preliminary matter, Plaintiffs note other federal courts' decisive dismissal of Dr. Levine's opinions about transgender people and the treatment of gender dysphoria. This began several years ago with the holding in *Norsworthy v. Beard*, that "the Court gives very little weight to the opinions of Levine, whose report misrepresents the Standards of Care; overwhelmingly relies on generalizations about gender dysphoric prisoners, rather than an individualized assessment of Norsworthy; contains illogical inferences; and admittedly includes references to a fabricated anecdote." 87 F. Supp. 3d 1164, 1188 (N.D. Cal. 2015). This holding was echoed in *Edmo v. Idaho Dep't of Corr.*, 358 F. Supp. 3d 1103, 1125-1126 (D. Idaho 2018) (vacated in part on other grounds in *Edmo v. Corizon, Inc.*, 935 F.3d 757 (9th Cir. 2019)) (holding that Dr. Levine

"is considered an outlier in the field of gender dysphoria" and gave "virtually no weight" to his opinions).

Dr. Levine's opinions were further diminished in *Hecox v. Little*, where the Court dismissed his opinion that "gender-affirming policies... are... harmful to transgender individuals," and instead "accept[ed] Plaintiffs' evidence regarding the harm forcing transgender individuals to deny their gender identity can cause." 479 F. Supp. 3d 930, 977 n.33 (D. Idaho 2020). And in just the last year alone, two more federal courts strongly discounted his proffered testimony by granting preliminary injunction motions against laws banning gender-confirming medical care and participation in school athletics, respectively, despite his testimony supporting those laws. *Brandt v. Rutledge*, 551 F. Supp. 3d 882 (E.D. Ark. 2021); *B. P. J. v. W. Va. State Bd. of Educ.*, 550 F. Supp. 3d 347 (S.D.W. Va. 2021). Against this backdrop, the deficiencies in Dr. Levine's opinions discussed below are all the more striking.

A. Many Of Dr. Levine's Opinions Will Not Help the Trier of Fact Because They Support Plaintiffs' Position.

Nearly all of Dr. Levine's opinions will not help the "trier of fact to understand the evidence or to determine a fact in issue," because, with very limited exception, he simply does not oppose the relief Plaintiffs seek. *Nease*, 848 F.3d 219, 229 (4th Cir. 2017) (cleaned up). For that reason, Dr. Levine's opinions do not "fit" with the facts relevant to resolving Plaintiffs' claims. *Bourne v. E.I. DuPont de Nemours & Co.*, 85 F. App'x 964, 966 (4th Cir. 2004).

Overwhelmingly, Dr. Levine's opinions and testimony are not contrary to the relief Plaintiffs seek in this case: that WV Medicaid participants with gender dysphoria receive coverage for gender-confirming surgery. Charles Decl., Ex. B at 86:25-87:19; 87:14-22; Ex. at C at 66:21-67:3; 69:18-70:2. Indeed, Dr. Levine testified that in just the last seven months, he has provided several letters of approval for gender-confirming surgeries for transgender people incarcerated at

Framingham, a correctional institution in Massachusetts. Charles Decl. Ex. B at 84:4-85:4. Dr. Levine has previously written similar letters for surgery in accordance with the medical community's widely accepted and authoritative guidance for transgender care, World Professional Association of Transgender Health ("WPATH") Standards of Care ("SOC"). Charles Decl., Ex. B. at 139:14-19; Ex. C at 55:13-17; 56:2-5; 112:16-21; 176:8-16; Ex. D at 1-100:15-22. He also recently testified that he does not provide such letters unless he has sufficiently informed his patients of possible risks and received a reasonable assurance that they understand. Charles Decl., Ex. C at 176: 8-16; 225:24-226:17. In fact, for almost fifty years, Dr. Levine's clinical practice has generally adhered to the WPATH SOC. Charles Decl. Ex. B at 136:8-11. And, as the WPATH's former Chairman of the SOC Committee, Dr. Levine helped to write Version 5 of the SOC, recognized his own writing in Version 7, and asked if he could help draft the forthcoming Version 8. Charles Decl., Ex. A at ¶67; Ex. B at 147:12-149:18. He testified at deposition in this case, and under oath previously, that he "is not advocating denying endocrine treatment or surgical treatment" to transgender people, a position he described as "draconian."

Dr. Levine testified at deposition that he is not offering *any* opinions in this case about whether Defendants should have an exclusion in their Medicaid program for coverage of gender-confirming surgery. Charles Decl. Ex. B at 86:25-87:19. He also testified that he does not feel his

³ Charles Decl., Ex. B 88:10-13; Ex. C at 73:4-7 ("Q: Is the worrisomeness about a patient's future health, is that a reason to ban all medical care for gender dysphoria? A: Absolutely not."); 84:21-85:1 ("Q: Given all those concerns you have, is that a reason to deny all medical interventions to people with gender dysphoria? A: No …"); 85:4-11 ("Q: Are those concerns you raised justifications in your mind for denying medical interventions to people who have gender dysphoria? A: You know, I'm not advocating denying endocrine treatment or surgical treatment."); 152:1-6 ("Q: Do you think because that study showed that some people committed suicide after gender affirming surgery that no patient should be able to access gender affirming surgery? A: That would be illogical"); 154:3-5 ("Q: But you're not recommending total bans on gender affirming surgery? A: I'm not recommending total bans."); 160:23-25 ("I did not say that gender affirming treatment in general should be stopped. I've never said that.").

"expertise extends to how the insurance industry works and how governments and legislatives work," nor "does he consider himself an expert" on whether Defendants' Exclusion should exist. Charles Decl., Ex. B at 87:14-22. These admissions contradict one of Dr. Levine's "key opinions" in his report, i.e., whether West Virginia's Medicaid Program should cover gender-confirming surgery, fundamentally undermining his credibility. Charles Decl., Ex. A at ¶10; Ex. B at 74:12-19. At bottom, Dr. Levine has repeatedly testified that he does not support banning gender-confirming medical care including surgery, which is the heart of Defendants' Exclusion. His opinions in this regard are thus consistent with the relief Plaintiffs seek and will not assist the trier of fact.

B. Certain Opinions Of Dr. Levine Have No Relevance To This Case Because They Address Issues Beyond The Scope Of The Dispute Or Have Already Been Addressed By The Fourth Circuit.

Dr. Levine's opinions fail to create any material disputes of fact because the relevance of Defendants' binding admissions refute his opinions. For example, Dr. Levine proposes to offer the opinion that "the biology of the person remains as defined by his (XY) or her (XX) chromosomes, including cellular, anatomic and physiologic characteristics..." Charles Decl., Ex. A at ¶18. But this case is simply a dispute asking whether a state Medicaid plan's categorical exclusion of gender-confirming care for transgender Medicaid participants that is covered for cisgender Medicaid participants discriminates based on sex and transgender status. The Court need not resolve questions about whether it is "biologically attainable" for transgender people to become "complete men or women," or whether sex is a binary concept. *Id.* at ¶17. The Court here need only decide whether Defendants can deny the same kinds of treatments to transgender Medicaid participants that it affords to cisgender Medicaid participants. Defendants' own Rule 30(b)(6) witness, Commissioner Cynthia Beane, testified that individuals enrolled in the Medicaid Program

can, she assumes, change their sex identification marker in Medicaid records. Charles Decl., Ex. E at 119:17-120:11. Therefore, even Defendants take no position on the issues in Dr. Levine's report about the etiology of sex, and instead use participants' self-reported gender identity as evidence of sex designation for the purposes of WV Medicaid enrollment and coverage.

Dr. Levine also offers the opinion, supported only by anecdotal narrative articles, that "gender exploratory" therapy can and has led to a resolution of gender dysphoria. Charles Decl. Ex. A at ¶37. But Commissioner Beane also testified that she was aware of the concept of "conversion therapy" and that no one, including transgender children, should be subjected to "that therapy." Charles Decl. Ex. E at 157:14-23. Significantly, Dr. Levine admits in his report that "quality evidence proving long-term effectiveness of psychotherapy interventions" such as those he advocates "is missing." *Id.* at ¶160. Defendants thus disagree with Dr. Levine's opinion, rendering it irrelevant, and he further admits it has no scientific basis.

Dr. Levine's opinions also do not help this Court because Fourth Circuit precedent informs review of the relevant issues. *See Grimm v. Gloucester Cnty. Sch. Bd.* 972 F.3d 586, 595 (4th Cir. 2020); *Kadel v. N. C. State Health Plan for Tchrs. and State Emps.*, 12 F.4th 422, 427 (4th Cir. 2021). His attempts to disparage the credibility of the WPATH and diminish the SOC as ideological and unscientific are directly contrary to the Fourth Circuit's reasoning in *Grimm*:

Fortunately, we now have modern accepted treatment protocols for gender dysphoria. Developed by the World Professional Association for Transgender Health (WPATH), the Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (7th Version 2012) (hereinafter "WPATH Standards of Care") represent the consensus approach of the medical and mental health community, Br. of Medical Amici 13, and have been recognized by various courts, including this one, as the authoritative standards of care, see De'lonta v. Johnson, 708 F.3d 520, 522–23 (4th Cir. 2013); see also Edmo, 935 F.3d at 769; Keohane v. Jones, 328 F. Supp. 3d 1288, 1294 (N.D. Fla. 2018), vacated sub nom. Keohane v. Fla. Dep't of Corrs. Sec'y, 952 F.3d 1257 (11th Cir. 2020). "There are no other competing, evidence-based standards that are accepted by any nationally or internationally recognized medical professional groups."

Edmo, 935 F.3d at 769 (quoting Edmo v. Idaho Dep't of Corr., 358 F. Supp. 3d 1103, 1125 (D. Idaho 2018)).

Grimm, 972 F.3d at 595-596. Further irreconcilable with available data and the consensus of the medical community, Dr. Levine suggests that the "high burden of mental illness" may be a "result" and/or "cause" of being transgender. Charles Decl., Ex. A at \$\infty\$35. The Fourth Circuit disagrees, reasoning that: "Being transgender is also not a psychiatric condition, and implies no impairment in judgment, stability, reliability, or general social or vocational capabilities." Grimm, 972 F.3d at 594 (cleaned up); see also Kadel, 12 F.4th at 427. Dr. Levine has previously testified at deposition that he believes that gender dysphoria, or being transgender, is a "product of other things," including possibly familial sexual abuse, distress over "their body changing," growing up in a single-parent home, or having an autism diagnosis. Charles Decl., Ex. C. at 154:5-8; 235:23-25; 137:10-13; 235:20-22; 235:17-20. The Fourth Circuit has also found that "[i]ust like being cisgender, being transgender is natural and is not a choice." Kadel, 12 F.4th at 427 (quoting Grimm, 972 F.3d at 594). Dr. Levine has previously admitted to practicing, and currently advocates for, the use of psychotherapy to "alleviate" gender dysphoria while withholding medical care, but the Fourth Circuit has acknowledged that "mental health practitioners' attempts to convert transgender people's gender identity to conform with their sex assigned at birth did not alleviate dysphoria, but rather caused shame and psychological pain." Grimm, 972 F.3d at 595. Essentially, Fourth Circuit precedent renders much of Dr. Levine's testimony irrelevant to this case.

C. Dr. Levine's Opinions That Do Not Support Plaintiffs' Position Are Methodologically Unreliable and Unsupported by Science or Medicine.

Expert testimony should only be admitted if its methodology is sufficiently reliable. *Sardis*, 10 F.4th at 281. Dr. Levine's opinions fall far short of each prong of this reliability standard. Dr.

⁴ Charles Decl., Ex. A at ¶37, ¶90

Levine admitted in his report and at deposition in this and other recent cases that theories upon which he relies lack any scientific support and have not been tested or subjected to peer review or publication. Charles Decl., Ex. A at ¶37, ¶160; Ex. B at 140:12-143:2, 145:19-25; Ex. C at 109:20-25; 116:4-7; 122:8-124:22; 131:11-132:1; 200:11-201:25. Even putting the *Daubert* reliability factors aside, although Dr. Levine claims his "experience" is sufficient foundation for his opinions, he fails to address how this purported experience leads to his conclusions and how such experience is reliably applied to the facts here. See, e.g., Cooper, 259 F.3d at 200 (affirming the exclusion of an expert because he "asserted what amounted to a wholly conclusory finding based upon his subjective beliefs rather than any valid scientific method."); Tyree, 54 F. Supp. 3d at 526 (excluding an expert witness when the only support offered for an opinion was clinician's experience and not any reliable data); SAS Inst., Inc. v. World Programming Ltd., 125 F. Supp. 3d 579, 589; see also Nat'l Ass'n. for Rational Sexual Offense L. v. Stein, No. 17-CV-53, 2021 WL 736375, at *3 (M.D.N.C. Feb. 25, 2021) (excluding expert where offering party failed to establish how expert's "experience leads to his conclusions nor how those experiences have been reliably applied to the facts").

1. Dr. Levine's Assertion that the WPATH SOC and Endocrine Society Guidelines Are Not the Authoritative Treatment Protocols for Gender Dysphoria Is Wrong.

Chief among Dr. Levine's many unreliable opinions is his assertion that the widely-accepted and utilized WPATH SOC and Endocrine Society Guidelines ("ESG") are not the authoritative treatment protocols for gender dysphoria. Seemingly contradicting *himself*, Dr. Levine has repeatedly testified, however, that he generally adheres to the WPATH SOC in his own clinical practice. Charles Decl., Ex. B at 136:8-11; Ex. C at 55:13-17; 56:2-5; 112:16-21; 176:8-16; 225:24-226:17; Ex. F at 29:10-18; 37:2-13; 47:22-49:3; 103:11-19. Nevertheless, Dr. Levine

attempts to undermine WPATH SOC by misrepresenting sources in his report and failing to include contrary information—undermining the admissibility and reliability of his opinions.

First, Dr. Levine alleges that the SOC are "very low quality and unfit tools for clinical decision-making," identifying one article by Dahlen et al. – but nowhere in that article does it characterize the WPATH SOC that way. Charles Decl., Ex. A at ¶21; Ex. G. The article concludes that the SOC are due for an update and acknowledges that evaluations of clinical practice guidelines in other medical areas including cancer, diabetes, pregnancy, and depression "tend to show room for improvement," and that "finding poor quality CPGs is not confined to this area of healthcare." Charles Decl., Ex. G at 8. In the same paragraph and without evidence, Dr. Levine makes a similar assertion about the ESG for treating gender dysphoria. Charles Decl., Ex. A at ¶21. Dr. Levine's report also mischaracterized the ESG's explanation of its "strong" versus "weak" recommendations related to gender-confirming care, something he admitted at deposition that he had no support for, reflected his own editorializing, and was not a quote from the Endocrine Society. *Id.* at ¶104; Charles Decl., Ex. B at 174:10-175:17

Second, Dr. Levine quotes from a *blog post* which mischaracterized comments from the incoming president of WPATH, Dr. Marci Bowers. Charles Decl., Ex. A at ¶23. Wholly absent from Dr. Levine's report was any acknowledgment of Dr. Bower's subsequent public statement released on her website that her comments were "taken out of context and used to cast doubt upon trans care," and her hope that those comments "will not be excerpted to weaponize ongoing attacks upon transgender persons." Charles Decl. Ex. H at 2. Third, Dr. Levine makes sweeping and inaccurate statements about WPATH SOC that other countries' protocols related to the treatment of gender dysphoria in transgender youth is evidence of a shift away from the WPATH SOC. Charles Decl., Ex. A at ¶22, 49. But again, Dr. Levine misrepresents even the content of non-peer

reviewed, non-scientific sources he uses to support this opinion. Both posts he cites to for this contention are from an advocacy group's website and plainly admit *in the text of the posts* that both Finland and Sweden allow youth to access medical interventions for the treatment of gender dysphoria, a fact Dr. Levine admitted at deposition. Ex. B at 106:4-108:8. Dr. Levine also acknowledged that the United Kingdom's Cass Review, which is currently underway, begins from the premise that some youth do experience gender dysphoria and will need clinical support and medical interventions, which are not prohibited in their health system. Charles Decl., Ex I; Ex. B at 191:20-192:16. Overwhelmingly, Dr. Levine's methodology and evidence for his opinions about the WPATH SOC do not meet the burden under *Daubert* or related standards articulated by this court for admissibility of expert witness testimony.

2. Dr. Levine's Opinions That Gender-Confirming Care Is Inadequate, Risky, and Without Lasting Benefit are Inaccurate and Unsupported.

Dr. Levine alleges that gender-confirming care is experimental, risky, and without lasting benefit. Charles Decl., Ex. A at ¶¶23, 39, 51, 118-122 This opinion cannot satisfy the reliability standard because Dr. Levine authorizes this care for his own patients and either ignores studies contrary to his belief or distorts their findings beyond the authors' explicit intentions or design. Significantly, he omits recent studies demonstrating that medical treatments for transgender adolescents and adults have favorable outcomes across many measures. Charles Decl., Ex. J. at ¶55. A plethora of studies also show that trans people experience pervasive stigma and discrimination, resulting in health disparities. But Dr. Levine omits any reference to those studies and instead implies that receiving gender-confirming care *causes* those disparities, such as increased risk of suicide and suicide attempts, relying most heavily on two articles which do not support this assertion. Charles Decl., Ex. A at ¶119-124. First, he relies on a study by Cecilia Dhejne, a scholar in the field who has publicly and specifically said Dr. Levine's assertion is a

mischaracterization of her work. Charles Decl., Ex. K at 65. Her study also does not support his assertion because *the study itself* states it is not designed to "address whether sex reassignment is an effective treatment or not." Charles Decl., Ex. L at 2. And when confronted at a recent deposition, he admitted the study design created a serious limitation in drawing any conclusions about the efficacy of the care. Charles Decl., Ex. C at 156:7-11. Dr. Levine makes similar implications in his report about the second study, Simonsen et al., suggesting that the article demonstrates higher death rates among people who received gender-confirming surgery. But again, the article states precisely the opposite, that "the present study design does not allow for determination of causal relations between HT (hormone therapy) and SRS (sex reassignment surgery) and somatic morbidity or mortality." Charles Decl., Ex. M at e65-e66.

Ultimately, Dr. Levine fails to cite any literature that supports this belief, and regardless, he confirmed that this should not prevent Plaintiffs or the class from receiving the relief they seek. When asked recently if he believes that because a study showed that some people committed suicide *no patient* should be able to access gender-confirming surgery, Dr. Levine responded, "that would be illogical." Charles Decl., Ex. C at 151:25-152:6. And when asked if all the concerns he has are justifications for denying medical interventions to all people with gender dysphoria, he responded "I'm not advocating denying endocrine treatment or surgical treatment." *Id.* at 85:4-11.

3. Dr. Levine's Opinions About Gender Dysphoria "Naturally Resolving" in Transgender Children and Adolescents Are Not Based In Fact.

Another unreliable opinion presented by Dr. Levine is that "the majority" of pre-pubescent children diagnosed with gender dysphoria will, absent intervention, cease to be transgender (or "desist") by adulthood. Charles Decl., Ex. A at ¶90. This opinion is unreliable and methodologically unsound for several reasons. First, Dr. Levine recently conceded that some

children are and will continue to be transgender and that as they progress into adolescence and adulthood, and that they would need medical care that he has, and would, authorize. Charles Decl., Ex. C. at 173:7-15; 137:14-23; 173:22-174:5; 53:16-54:7. Second, for this opinion, Dr. Levine cites to three articles that share the same core methodological flaw: they discuss studies that only include children whose gender non-conforming behavior was diagnosed under the obsolete and overly broad diagnostic criteria for "Gender Identity Disorder in Children" of the Diagnostic Statistical Manuals ("DSM") III, III-R, IV, and IV-R. Charles Decl., Ex. A at ¶90 nn.130-132. Under these sweeping, outdated diagnostic criteria, and the thinly veiled anti-gay attitudes of many clinicians at the time who viewed being gay as a disorder, most of the children diagnosed with Gender Identity Disorder in Children were not actually transgender but were gay or bisexual. Because of the years of initial visits in the study samples (1952-2008) none of these children were diagnosed under the diagnostic criteria for "Gender Dysphoria in Children," contained within the current and authoritative DSM-V, released in 2013, which requires "a strong desire to be of the other gender or an insistence that one is the other gender" and "clinically significant distress or impairment in social, school, or other important areas of functioning." Charles Decl., Ex. N at 452. Therefore, the "desistance rates" from the studies upon which Dr. Levine bases his opinion reflect children who, while they might have exhibited cross gender behaviors, would not satisfy the current diagnostic criteria and were likely not even transgender, or suffering from gender dysphoria. This clear implication undercuts other of Dr. Levine's conclusions but most importantly underscores that Dr. Levine cannot be established as a reliable expert because he manipulates available research and "cite[s] papers that do not provide the support asserted." *Tyree*, 54 F. Supp. 3d at 520 (cleaned up).

Dr. Levine also attempts to undercut the validity of the authoritative and widely used

diagnostic criteria for gender dysphoria in the DSM V. Charles Decl., Ex. A at ¶86. Without any evidence, Dr. Levine characterizes the International Classifications of Diseases Version 11 ("ICD-11") as a "diagnostic category [sic]," "which is expected to supersede DSM-V in determining eligibility for transgender interventions." *Id.* Setting aside that Dr. Levine again provides no citation or scientific proof of this assertion, the truth is that the ICD-11 has not even been adopted in the United States. Charles Decl., Ex. O at 108:10-18. Dr. Levine's claim that the "conflict" between the two precludes being able to determine medical necessity is an exercise in fiction. Indeed, the screening tool that BMS uses to determine medical necessity has issued policies clearly indicating when this care is medically indicated. Charles Decl., Ex. P. Such hypothetical and scientifically unsupported ideas cannot be the basis for reliable expert testimony.

4. Dr. Levine's Assertion that "Rapid Onset Gender Dysphoria," as a Cause of Gender Dysphoria or the Concept of "Detransition" Justifies Denying Treatment to Transgender WV Medicaid Recipients Who Need It Is Unsupported By Scientific Evidence.

A stark example of Dr. Levine's opinions failing to meet methodological reliability is his assertion that the untested and scientifically unsupported hypothesis of "rapid onset gender dysphoria" justifies denying Medicaid coverage of medical interventions to Plaintiffs and the proposed class. Charles Decl., Ex. A at ¶79. "While hypothesis is essential in the scientific community because it leads to advances in science, speculation in the courtroom cannot aid the fact finder in making a determination" *Dunn v. Sandoz Pharms. Corp.*, 275 F. Supp. 2d 672, 684 (M.D.N.C. 2003). Just seven months ago, the only article Dr. Levine could name regarding "rapid onset gender dysphoria" was withdrawn and republished with a significant correction that Dr. Levine confessed he had not read. Charles Decl., Ex. C at 116:22-117:9. The correction admitted that: "rapid onset gender dysphoria is not a formal mental health diagnosis," "the report did not collect data from adolescents and young adults or clinicians and therefore does not validate

the phenomenon," and "the use of the term, 'rapid onset gender dysphoria' should be used cautiously by clinicians and parents to describe youth." Charles Decl., Ex. Q at 1. Indeed, several months later, Dr. Levine does not cite to any new peer reviewed sources or studies that establish evidence of such a phenomenon, but instead to *one* article merely suggesting research should be performed. Charles Decl. Ex. A at ¶79. Despite this, at deposition Dr. Levine attempted to conflate an increased number of transgender young people presenting to clinics for care with the theory of "rapid onset gender dysphoria" and asserted, without evidence, it is not a hypothesis but "a fact," that he "assumes everyone understands [this] is true." Charles Decl. Ex. B at 151:18-152:6, 152:22-153:5. When pressed to provide peer-reviewed articles, sources, or studies as scientific support he referenced presentations without title or date, admitted he could not remember the names of "authors from Europe" but asserted it had been documented by "DiAngelo and Clayton in Australia." To date, the *only* peer-reviewed study that interrogates this hypothesis using adolescent clinical data "did not support the ROGD hypothesis." Charles Decl., Ex. R at 1.

Similarly, when confronted at deposition about his opinion that there is "evidence that *a growing number* of young people regret transition and wish to reverse it," Dr. Levine admitted he lacked any scientific support for such an opinion. Charles Decl., Ex. A at ¶79; Ex. B at 158:8-159:2; 160:25-161:9; 163:9-24. Dr. Levine did not point to his own experience as a basis and conceded three times that the sources he cited in his report did not provide relevant evidence. *Id.* Even if Dr. Levine had relied on his own experience for this opinion, "a reliable expert would not ... misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted." *Tyree*, 54 F. Supp. 3d at 520 (cleaned up).

Seven months ago, when confronted about the same "detransition subreddit" that Dr. Levine cites in his report here, he admitted he had no evidence that *even one* of the then 16,000

members of the subreddit had actually "detransitioned." Charles Decl., Ex. C at 200:6-201:25. Nothing has changed in the intervening months except that now Dr. Levine concedes in his report that "it would be wrong to assert that each of the members have detransitioned." Charles Decl., Ex. A at ¶91. Despite this concession, he asserts without citation or evidence that "it is reasonable to assume that many are considering it, and many have accomplished some degree of it." *Id.* Why Dr. Levine believes it is "reasonable" for an expert witness to make unsupported assumptions is unclear, but this does not pass *Daubert* muster. Given that these hypotheses about "rapid onset gender dysphoria" and ideas about "detransition" are entirely unverified or unsupported, Dr. Levine cannot claim that they use any reliable methodology. His reliance on his own *ipse dixit* fails to establish a basis upon which to assert this opinion.

D. Dr. Levine Is Not Qualified To Offer Opinions About the Cost of Gender-Confirming Care, Or About Puberty-Delaying Treatment Or the Treatment of Pre-Pubescent Transgender Children Generally.

Although Dr. Levine opines about the cost of gender-confirming care, he admits that—whatever his skills may be— "economic analysis is not one of them. Others must be relied upon to answer the question." Charles Decl. Ex. A at ¶55. Dr. Levine's candid admission that he is unqualified to render this opinion alone should disqualify it, but his analytical errors end all doubt.

Dr. Levine begins his analysis by stating that "the data already show that the numbers of individuals seeking transgender interventions on West Virginia Medicaid increased from 30 individuals in 2016, to 686 individuals through the end of September in 2021." Charles Decl. Ex. A ¶54. He relies on a discovery response by Defendants providing those figures, suggesting that this increase over a 5-year period supports his ideas about a "rapid rise in transgender identification, especially among youth." Charles Decl. Ex. A at ¶53. But he makes two fatal omissions.

First, he fails to disclose that the increase may be because West Virginia Medicaid began covering hormone therapy for gender-affirming care in 2017, one year into that period, as described in Plaintiffs' motion for summary judgment. Accordingly, this supplies no reliable basis to infer a "rapid rise in transgender identification."

Second, Defendants were asked in Plaintiffs' Second Set of Interrogatories to "identify the number of Health Plan participants who have submitted one or more claims with a diagnosis code for Gender Dysphoria or Gender Incongruence." Charles Decl. Ex. S at ¶11. Significantly, Defendants did not specify, and Dr. Levine does not purport to know, how many claims were for services like psychotherapy and hormone replacement therapy, and which were for services barred by the Exclusion. To this point, Dr. Levine admitted at deposition that not only does he not know which of the 686 Medicaid participants need which kinds of "interventions", but he also does not know which participants need surgery. Charles Decl. Ex. B at 213:20-25; 212:15-17.

Dr. Levine also provides no evidence of how many of the 686 participants claims are from youth or adults. But he suggests, without evidence or any basis upon which to opine, that "the majority" of transgender people will choose to undergo medical interventions, and that the proportion will increase "when such interventions are provided at no cost to the patient" or, as he implies, if WV Medicaid removes the Exclusion. Charles Decl., Ex. A at ¶53. Similarly, and without evidence or scientific methodology used to reach this conclusion, Dr. Levine wildly suggests that "as many as 30,000 West Virginia youth could be identifying as transgender." *Id.* at ¶54. What this has to do with West Virginia's Exclusion of gender-confirming surgery and its cost is murky at best and is certainly an opinion that should be excluded from testimony before this court. At bottom, Dr. Levine disclaimed at deposition that he was offering any opinions about how

the WV Medicaid program is subsidized by the federal government, about the cost of puberty blockers under the West Virginia Medicaid Program, or about the cost of surgical care for the treatment of gender dysphoria under the West Virginia Medicaid Program. Charles Decl. Ex. B at 211:17-21; 210:13-19; 211:6-10. The Court should accept Dr. Levine's own admissions that he is neither qualified to opine, nor opining about, the cost of gender-confirming care, and exclude such testimony as unfounded and irrelevant.

Dr. Levine also offers unsupported personal beliefs about the impact of puberty delaying treatment, for which he lacks clinical, and as his report admits, scientific evidence. Charles Decl. Ex. A at ¶132. Without citation, Dr. Levine raises the specter of puberty delaying medication causing transgender children "diminished sexual response," and extrapolates his unsupported opinion even further to suggest that youth will experience "social, psychosocial, and interpersonal impacts" of "not being in puberty for 2-5 years." *Id.* at ¶131, 132, 134. But Dr. Levine admits he lacks published data for these theories which, "have not been systematically studied." *Id.* at ¶132, ¶135. In fact, Dr. Levine's only consistent citations for these opinions are two of his own publications, which do not contain research, studies, or data that he has collected or analyzed. *Id.* at nn. 207, 208, 211, 213, 215. Dr. Levine again suggests that it is "reasonable to assume" that puberty delaying treatments "increase the adolescent's sense of isolation otherness or being an outsider." *Id.* at ¶136. Contrary to Dr. Levine's suggestion, unsupported assumptions are not an acceptable basis for expert testimony by this Court and fall far short of the standard for reliability.

Unsurprisingly, this is the norm for Dr. Levine's proffered opinions in other cases. He recently testified that puberty delaying treatment should not be available to any transgender adolescents because in the cases he has seen, such treatment was "like a treatment for the mother's pathology, not for the child." Charles Decl., Ex. C at 184:25-185:2. If it were up to Dr. Levine, he

would "consider banning puberty blocking hormones even for children who have been cross-gender identified for four years to give them a chance to desist." Charles Decl., Ex. C at 186:20-25. Even Dr. Levine acknowledges the unscientific nature of this opinion, as he recently admitted he does not know where it comes from or "to what extent it's from my politics, or from my being a parent or a doctor, I don't know." Charles Decl., Ex. C at 187:20-24.

Dr. Levine has also repeatedly admitted at depositions for the last year—as he must—that he has no experience performing research or publishing studies about pre-pubescent transgender children, and virtually no experience administering psychiatric treatment to them. Charles Decl., Ex. A at ¶5; Ex. B at 26:10-13; Ex. C at 23:1-8. When asked whether he has treated any children with gender dysphoria, he admitted, "I have only on rare occasion personally treated or directly or indirectly treated a child." Charles Decl. Ex. B at 28:23-29:6; 62:6-14. Dr. Levine also confirmed his testimony from March 30, 2022, that over the course of his nearly 50-year career, he had only seen an estimated six pre-pubertal children, and not for more than one visit. Charles Decl., Ex. T at 87:1-7. When asked about more recent experience treating children with gender dysphoria, Dr. Levine confirmed his testimony from seventh months ago was correct and that in the intervening months he had not treated any children. Charles Decl., Ex. B at 77:24-78:6; Ex. C at 51:14-18; 52:14-22. When asked if Dr. Levine had helped to develop guidelines for the treatment of transgender children or adolescents with gender identity issues he responded "the answer is no." Charles Decl., Ex. B at 51:10-16. Dr. Levine is not recognized as an expert in providing treatment to transgender children by his private employer who by his own admission does not refer children to him as patients, nor by the University Hospitals' LGBTQ and Gender Care Program--the Cleveland hospital affiliated with Case Western Reserve University Medical School where Dr. Levine is a clinical professor—which he previously admitted did not consult with him as part of its formation or their ongoing work. Charles Decl., Ex. T at 113:19-114:4. He does not write or research about providing treatment to transgender children, nor does he deliver any psychiatric care to them in his day-to-day practice. Dr. Levine is not qualified under the *Daubert* standards to offer opinions on matters relating to the care of transgender children, and he cannot use his personal beliefs as methodologically reliable evidence.

E. Dr. Levine's Report, Opinions, And Testimony Lack Probative Value And Are Thus Inadmissible Under Federal Rule Of Evidence 403.

Finally, the Court should exclude evidence if its introduction will result in unfair prejudice, confusion of the issues, or result in misleading testimony. Fed. R. Evid. 403. As noted above, Dr. Levine offers no opinions on any factual dispute in this case, and, in any event, the opinions he offers are irrelevant and unreliable. Consideration of his testimony would waste time and create confusion. The testimony would also result in prejudice, as the testimony seeks to sow confusion about the veracity of Plaintiffs' gender identity, gender dysphoria diagnosis, and other experiences—issues unrelated to whether the WV Medicaid Program can deny coverage of the same kinds of treatments to transgender people that it provides cisgender people. Accordingly, Dr. Levine's testimony fails to satisfy the requirements of Fed. R. of Evid. 403 and should be excluded.

IV. CONCLUSION

Plaintiffs respectfully request that this Court grant the instant motion and exclude all of Dr. Levine's purported expert testimony as inadmissible under *Daubert* and the Rules of Evidence.

Dated: May 31, 2022

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IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA HUNTINGTON DIVISION

CHRISTOPHER FAIN, et al., individually and on behalf of all others similarly situated,

Plaintiffs,

v.

WILLIAM CROUCH, et al.,

Defendants.

CIVIL ACTION NO. 3:20-cv-00740 HON. ROBERT C. CHAMBERS

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document, and any attachments, were served electronically on May 31, 2022 on the following counsel for Defendants in this case:

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